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| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
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EXAMINER

0M61/0621

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FORD, J

| ART UNIT | PAPER NUMBER |
|---|---|
| 3743 | 13 |

DATE MAILED: 06/21/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

## OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 3-22-99

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) 1-20, 22-35 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☐ Claim(s) _____ is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 1-20, 22-35 are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

**–SEE OFFICE ACTION ON THE FOLLOWING PAGES–**



★ U.S. GPO: 1996-421-632/40206

Applicant's election of the species of Figure 5 in Paper No. 14 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-20 and 22-35 have been identified as readable on the elected species of Figures 1 and 2. Applicant continues to pursue apparatus claims inspite of the examiner's discussion of the perils in Paper No. 14.

Legible drawings have been received.

Materials intended to be worked upon or used in an apparatus are not given patentable weight in a claim drawn to the apparatus, for the reasons discussed in Paper No. 14, page 2.

Claims 1-20 and 22-35 are examined here. All other claims have been canceled.

Claims 1-20 and 22-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the description of Figures 1 and 2 in the specification element 8 is the "structure" and elements 6 are the "fins". 37 CFR 1.75 (d)(1) requires that claim phrases find clear antecedent basis in the specification. What is called a "heat exchange member" in the claims is actually a "fin" by disclosure. Please change the recitation to -- heat exchange fin -- so that ~~thread~~ reader will understand what disclosed element is being claimed. It is noted that the word "structure" is very broad by its dictionary definition and applicant is put on notice that this word will be given its dictionary meaning in the absence of any other limitations placed on it.

While it may not even be a consideration in the rejections which follow the term "biopharmaceutical product" is vague particularly in light of what is stated in the specification to constitute a "biopharmaceutical product". Proteins, cells, blood, plasma, antibodies, medicines buffer solutions, viruses, serum, cell fragments cellular components are identified as "biopharmaceutical products". By it own terms however this definition is a non-exclusive list. See page 7 of the specification ,lines 1-6. A "pharmaceutical" in the Examiner's dictionary means "of or pertaining to pharmacy or pharmacists" or "a pharmaceutical product or preparation". Pharmacy is, by dictionary definition= "the art of preparing and dispensing drugs". Thus a "biopharmaceutical" (a word not in the examiner's dictionary) must be a drug made from living organisms. Most of the things on applicant's list don't fit this definition of biopharmaceuticals. How is a buffer (water with some acid or base dissolved it) a "biophamaceutical product". What is its value as a drug? How is it made by a living organism? How would a person's blood, plasma be a drug? It is true that viruses can be genetically engineered to be "drugs" but how would the freezing of such a virus be any different front a genetically unaltered virus which has no "drug" value. The definition and the contractory examples applicant has put forth on page 7, lines 1-7 has made an essentially ambiguous limitation in the claim, if it carries any weight at all in a claim drawn to the apparatus.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20 and 22-35 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Longardner et al (Figures 11-13).

Longardner in the relied upon Figures shows a heat exchange member (260) extending centrally having a plurality of fins (264) attached to it. These fins are closely located to fins (272) attached to the wall of the tank. Regarding claim 7, the examiner does not see a removable liner in the elected specie. Please designate it nonelected or show where it is disclosed in reference to the elected specie of Figure 5 and illustrate it a proposed drawing correction.

The substance being frozen, thawed or otherwise being temperature conditioned does not impart patentability to an otherwise inanimate heat exchange apparatus. See the cases cited at the beginning of this office action and in the previous office action. Regarding the formation of dendrites, the structure disclosed would inherently possess this property if the material to be frozen is one which forms crystals by nature.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Longardner as applied to claim 1 above, and further in view of Brown (Figure 2).

Brown teaches a helical flow path in the jacket. To have modified the jacket of Longardner with such a helical path would have been obvious to improve efficiency.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-20 and 22-35 are rejected under 35 U.S.C. 102((b)(a)) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the Wiosniewski and Wu article entitled Large-scale freezing and ~~throwing~~ thawing of Biopharmaceutical Products and the underlying use known to other of the experimental pilot-scale equipment disclosed on page 22 of that article (Fig. 2.2) or the setup on page 24 (Fig. 25) or the unit show in (Fig. 2.9).

It appears that Mr. Wu, an employee of Genentech was associated with much of the early work in this area. Assuming the publication is prior art as to the inventors here, it is anticipatory. As well a public use (in the Genentech company) may have taken place with the aforementioned pilot and other equipment discussed in the reference.

Any inquiry concerning this communication should be directed to John Ford at telephone number (703) 308-2636.

John K. Ford
Primary Examiner

J. FORD:LM
OCTOBER 04, 1999